

**Remarks**

This is responsive to the Office Action mailed on March 7, 2006.

Claims 1 and 52-59 have been amended to clarify the claim language. The claims were amended to recite that the method pertains to identifying a compound capable of binding to *active site of RRF* protein. Claim 1 was further amended to recite that the method includes employing a three-dimensional structure of RRF protein as *produced by a computer* using atomic coordinates of RRF protein according to Table 8. Support for this amendment can be found throughout the specification, such as in Example 3 (pp. 41-45) and at page 26, line 15 to page 27, line 14 (particularly page 26, lines 20-22 and page 27, lines 2-5). In addition, claims 1 and 57 were amended to correct minor typographical errors.

As a result, claims 1 and 52-59 are pending for examination, with claim 1 being the sole independent claim. No new matter has been added.

**Statement of Substance of Interview**

Applicant thanks the Examiner for the interview granted on May 12, 2006.

Applicant, Applicant's representative and the Examiner discussed the outstanding rejections. Proposed amendments were presented and discussed, including limiting the claims to RRF active site binding based on the Examiner's suggestions in the Office Action regarding scope of enablement. Discussion of In re Gulack included a discussion of the differences in the technology of Gulack and that of the present invention. In addition, Applicant noted that the court found that the Gulack invention was patentable. Applicant's representative indicated that other case law does not favor application of "printed matter" rejections in computer-based technologies.

Applicant provided a description of the invention and its usefulness in designing inhibitors of bacteria. In addition, Applicant described how others have used structural coordinates for other proteins in designing and identifying binding compounds. Applicant also discussed the software available for utilizing structural coordinates to generate a three-dimensional structure to facilitate compound identification.

#### **Rejections Under 35 U.S.C. 112, Second Paragraph**

The Examiner rejected claims 1 and 52-53 under 35 U.S.C. 112, second paragraph, as indefinite. Applicant has amended claim 1 to recite “step”, and accordingly respectfully requests reconsideration and withdrawal of the rejection.

#### **Rejections Under 35 U.S.C. 112, First Paragraph**

A. The Examiner rejected claim 57-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement on the basis that these claims contain new matter. Applicant respectfully traverses the rejection.

The Examiner stated that Applicant had not provided support for the amendments to claim 57, because the description in the specification allegedly only shows specific species of inhibitor screening methods, which the Examiner believes do not support the genus of binding assays recited in claim 57.

Applicant respectfully disagrees, and notes that claim 57 does not recite binding assays or inhibitor assays per se. Instead, claim 57 as presently amended recites “...contacting said compound capable of binding to the active site of RRF protein with said RRF protein in the presence of a substrate to determine the ability of said compound capable of binding to the active site of RRF protein to bind the active site of said RRF protein”. Thus claim 57 recites contacting a compound with RRF protein. This is supported in the specification, for example, on page 12,

lines 15-17: "Further, the present invention relates to use of the RRF protein for measuring binding interaction between a compound and the RRF protein." Thus determining binding between compounds and RRF is clearly provided and adequately described in the specification.

Thus, claim 57 is fully supported in the specification as filed. Reconsideration and withdrawal of the rejection is respectfully requested.

B. The Examiner rejected claims 1 and 52-59 under 35 U.S.C. 112, first paragraph, as not enabled. Applicant has amended the claims to recite that the compound binds to the active site of RRF protein. The Examiner agreed that the specification provided the active site residues of RRF protein.

The person of skill in this particular art is highly skilled. Thus, the identification by Applicant of the crystal structure, the active site, and even specific amino acid residues present in the active site is sufficient for the skilled person to carry out the claimed methods. The skilled person, moreover, is well aware of the techniques and methods used in carrying out the claimed invention.

Therefore, based on the claim amendments, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 52-59 under 35 U.S.C. 112, first paragraph, as not enabled.

#### **Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 1 and 52-59 under 35 U.S.C. § 103 as unpatentable over US patent 5,856,116 (Wilson et al.) in view of In re Gulack, 703 F.2d 1381, 217 USPQ 401 (CAFC 1983). Applicant respectfully traverses the rejection and requests reconsideration.

The use of the Gulack case has been commented on in other legal decisions. One of particular note is In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994). Regarding the use of “printed matter” rejections, the court stated the following:

“As an initial matter, this court notes that Gulack cautioned against a liberal use of ‘printed matter rejections’ under section 103:

A ‘printed matter rejection’ under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. . . . [The Court of Customs and Patent Appeals], notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated. Gulack, 703 F.2d at 1385 n.8.

Despite this cautioning, the Board erroneously extended a printed matter rejection under sections 102 and 103 to a new field in this case, which involves information stored in a memory. This case, moreover, is distinguishable from the printed matter cases. The printed matter cases ‘dealt with claims defining as the invention certain **novel arrangements of printed lines or characters, useful and intelligible only to the human mind.**’ In re Bernhart, 417 F.2d 1395, 1399, 163 USPQ 611, 615 (CCPA 1969) (emphasis added). **The printed matter cases have no factual relevance where ‘the invention as defined by the claims requires that the information be processed not by the mind but by a machine, the computer.’** Id. (emphasis in original). Lowry’s data structures, which according to Lowry greatly facilitate data management by data processing systems, are processed by a machine. Indeed, they are not accessible other than through sophisticated software systems. The printed matter cases have no factual relevance here.”

Applicant respectfully directs the Examiner’s attention to the bolded sentences above, in which the CCPA and CAFC have stated that printed matter cases pertain to “novel arrangements of printed lines or characters, useful and intelligible only to the human mind” and “[t]he printed matter cases [i.e., Gulack] have no factual relevance where ‘the invention as defined by the claims requires that the information be processed not by the mind but by a machine, the computer.’”

The structural coordinates are processed by a machine, i.e., a computer running software, and not by the human mind. Based on this distinction between printed matter and computer-implemented inventions by the court in In re Lowry, Applicant has amended claim 1 to include that the three-dimensional structure is produced by a computer.

Applicant finally notes that although the Examiner relies on the Trilateral Project WM4 Report, that Report should not sustain the rejection because Applicant's claims, as amended, fall squarely within the precedent of In re Lowry.

Although mindful that each patent stands on its own, as additional evidence that the use of a protein structure as defined by atomic coordinates is indeed patentable in view of In re Gulack, Applicant notes that US patents have been granted to the use of structural information of a known protein. Three examples of such patents are: US 6,183,121, US 6,303,287 and US 6,387,641. In all of these patents, the intention is the same as the present invention; use of patented structural information to device new compounds which binds to the protein using known computer algorithm.

Accordingly, in view of the foregoing arguments and the amendment of the claims, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims as unpatentable over US patent 5,856,116 (Wilson et al.) in view of In re Gulack.

**CONCLUSION**

In view of the foregoing amendments and arguments, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,  
***Kaji, et al., Applicant***

By:



John R. Van Amsterdam, Reg. No. 40,212  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 646-8000

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